

specification by inserting reference to a specific accession number. The reference in the specification to "[c]ultures of group A variant streptococcus, which produce the above polysaccharide structure are deposited with the American Type Culture Collection" encompasses several different variants of group A streptococcus which all make polysaccharide having group A structure. For example, applicants provide copies of pages 209 and 210 of the American Type Culture Collection *Catalogue of Bacteria and Phages*, Seventeenth Edition, 1989 which provides a number of variants of *Streptococcus pyogenes* which are identified as Lancefield's Group A. Thus, one of ordinary skill in the art could easily obtain the polysaccharide for use according to the invention from several different strains.

Response to Section 112 Rejection

Claims 61-72 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as their invention. In particular, claims 61, 62 and 63 are rejected for being vague for reciting the term "about," and claims 62, 67 and 68 are rejected for improper antecedent basis. Applicants respectfully disagree with the Examiner's rejection of the claims for being vague.

Applicants have amended claims 62, 67 and 68 to address the Examiner's concerns. However, applicants respectfully submit that the rejection of claims 61, 62 and 63 is improper. The fact that claim language includes terms of degree does not necessarily render the claim indefinite under 35 U.S.C. § 112., second paragraph. See *Seattle Box Co. v. Industrial Crating & Packing, Inc.*, 731 F.2d 818, 221 USPQ 568 (Fed.Cir. 1984). Acceptability of the claim language depends on whether one of ordinary skill in the art would understand what is claimed in light of the specification. MPEP 2173.05(b). The metes and

bounds of the present claims are clear to one of skill in the art. That one of skill in the art is reasonably appraised of the scope of the invention when claims recite group A streptococcal polysaccharides having from about 3 to about 30 repeat units, applicants refer to U.S. Patent No. 5,866,135 which describes group A streptococcal polysaccharides having from about 3 to about 30 repeat units. Applicants assert that the term "about" as used in the currently pending claims is also clear to one of skill in the art and, therefore, that the claims are definite. In light of the amendments and arguments presented above, applicants request reconsideration and withdrawal of the Section 112 rejection.

Response to Section 102 Rejection

Claims 61-63, 68 and 69 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Reimer et al. (1992) *Carbohydrate. Res.* 232:131. The Examiner contends that Reimer describes a method of immunizing a rabbit with a branched trisaccharide or pentasaccharide covalently linked or conjugated to a protein. Reimer does not refer to the use of polysaccharides of group A streptococcus comprising about 3 to about 30 repeat units wherein each repeat unit is a trisaccharide moiety. Reimer does not teach a polysaccharide having even two repeat units. Accordingly, applicants respectfully disagree with the Examiner's rejection.

For a reference to anticipate a claim it must teach each and every element of the claim. Reimer does not teach applicants method of immunizing with the claimed protein polysaccharide conjugate because Reimer does not teach the protein polysaccharide conjugate used in the claimed method. Accordingly, the Section 102 rejection is improper and its withdrawal is respectfully requested.

Response to Section 103 Rejection

Claims 61-72 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Reimer et al. (1992) *Carbohydr. Res.* 232:131 in view of Jennings et al. U.S. Patent 4,356,170 and Barnes et al. WO 87/06590. In particular, the Examiner contends that it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to modify Reimer, Jennings and Barnes with a reasonable expectation of success. Applicants respectfully disagree with this rejection.

To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

The Examiner has not provided evidence of any suggestion or motivation to modify or combine the references. More importantly, the Examiner has failed to show a reasonable expectation of success. As explained by Dr. McCarty in his Declaration (filed December 8, 1999), even though the group A streptococcal polysaccharide was known, the art did not consider it to be relevant in connection with eliciting a protective immunogenic response in individuals. See paragraph 6. Dr. McCarty who was associated with Dr. Lancefield who first discovered the group A carbohydrates, states that although the carbohydrate had been demonstrated as a major constituent of the bacterial cell wall, it was not considered to generate a response which would protect the host against invasiveness of the

organism. See paragraphs 7 and 8. Thus, prior to applicants' invention, there was no motivation to consider the use of the group A streptococcal polysaccharide in the various compositions and methods claimed by applicants. None of the publications cited by the Examiner provide this motivation.

In order to sustain a rejection under 35 U.S.C. § 103, the references themselves, independent of the application, must provide a motivation to combine them to arrive at the ground of rejection. Since prior to applicants' invention, the state of the art did not appreciate the protective activity of antibodies against group A polysaccharide, and in fact, as shown in the McCarty Declaration, had been led to believe that the polysaccharide was not involved in generating a protective response, there was no motivation to combine the references as suggested by the Examiner.

Moreover, issuance by the U.S. Patent Office of U.S. Patent No. 5,866,135, directed to polysaccharide fragments and their use as vaccines demonstrates the patentability of the presently pending claims as methods of use of the patentable polysaccharides should not make them any less patentable.

Finally, the combination does not teach or suggest all the claim limitations. Neither immunizing against infection nor the polysaccharide protein conjugate are taught or suggested in the combination of cited prior art. Therefore, applicants request reconsideration and withdrawal of the Section 103 rejection.

Response to Claim Objections

Claims 61, 63, and 70 stand objected to for the recitation in claim 61 of "to protein." Applicants have amended claim 61 to recite "to a protein" as requested by the Examiner, which amendment is not intended to alter the scope of the claim. Withdrawal of the

objection is respectfully requested.

Claim 70 stands objected to for the use of the abbreviation "QS21." Applicants respectfully disagree with this rejection. "QS21" is the common name for the adjuvant. An adjuvant is a substance added to a vaccine to improve the immune response. "QS21" is the name used by those skilled in the art. The term is definite. Withdrawal of the objection is respectfully requested.

AUTHORIZATION

The Commissioner is requested to grant a petition for any extension of time which is required to make this response timely and is hereby authorized to charge any fee for such an extension of time or credit any overpayment for an extension of time to Deposition Account No. 13-4500, Order No. 2016-4005US1. A DUPLICATE COPY OF THIS SHEET IS ATTACHED.

Respectfully submitted,

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